

# **EXHIBIT A**

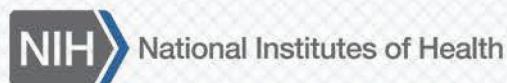


# NIH GRANTS POLICY STATEMENT

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US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH



APRIL 2024



## PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

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### Subpart A: General

## 3 OVERVIEW OF TERMS AND CONDITIONS

Part II includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards. Subpart A (IIA) includes those terms and conditions that apply, in general, to NIH awards. Subpart B (IIB) either expands on IIA coverage or specifies additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

[NIH recipients are responsible for complying with all requirements of the Federal award.](#) NIH grants awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in the NoA.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in [appropriations acts](#). This also includes any recent legislation.
- 2 CFR Part 200.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIHGPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

This NIHGPS is an aid to the interpretation of statutory and regulatory requirements. These terms and conditions are intended to be compliant with governing statutes and the requirements of 2 CFR Part 200, as modified by previously approved waivers and deviations. However, in the case of a conflict, the statutes and regulations govern.

If there is a perceived conflict between or among these three categories of requirements—statutory and regulatory requirements, the terms and conditions in the NIHGPS, and award-specific terms and conditions—or if the recipient has other questions concerning award terms and conditions, the recipient

should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the recipient not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the recipient agrees to the terms and conditions of the award.

### **3.1 FEDERALWIDE STANDARD TERMS AND CONDITIONS FOR RESEARCH GRANTS**

In order to create greater consistency in the administration of Federal research awards, all Federal research agencies now utilize a standard core set of administrative terms and conditions on research and research-related awards that are subject to 2 CFR Part 200, to the extent practicable. The core set of administrative requirements for participating Federal research agencies and other pertinent documents are posted on the [National Science Foundation's web site](#). Recipients are encouraged to review the companion documents which include a Prior Approval Matrix, National Policy Requirement Matrix, Subaward Requirement Matrix, and Agency-Specific Requirements. NIH implementation of these Federalwide research terms and conditions is also known as the "NIH Standard Terms of Award".

See [Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award](#) for more details.



before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing specific conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

### **8.5.1 Specific Award Conditions: Modification of the Terms of Award**

During grant performance, the GMO may include specific award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When specific conditions are imposed, the GMO will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR Part 52.9 and 2 CFR Part 200.339.

The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case, the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel.

Generally, the decision to modify the terms of an award (e.g., by imposing specific award conditions) is discretionary on the part of the NIH awarding IC and is not appealable.

### **8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support**

If a recipient has failed to comply with the terms and conditions of award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action. NIH may also terminate the grant in whole or in part as outlined in 2 CFR Part 200.340. The regulatory procedures that pertain to suspension and termination are specified in 2 CFR Parts 200.340 through 200.343.

- a. NIH or the pass-through entity must provide the non-Federal entity a notice of termination
- b. If the award is terminated for the non-Federal entity's material failure to comply with the Federal statutes, regulations, or terms and conditions of the Federal award, the notification must state that:
  1. The termination decision will be reported to the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS);
  2. The information will be available in the OMB-designated integrity and performance system for a period of five years from the date of the termination, then archived;
  3. Awarding agencies that consider making a Federal award to the non-Federal entity during that five year period must consider that information in judging whether the non-Federal entity is qualified to receive the Federal award, when the Federal share of the Federal award is expected to exceed the simplified acquisition threshold over the period of performance;
  4. The non-Federal entity may comment on any information the OMB-designated integrity and performance system contains about the non-Federal entity for future consideration by HHS awarding agencies. The non-Federal entity may submit comments to the recipient integrity and performance portal accessible through CPARS.
  5. Federal awarding agencies will consider the non-Federal entity comments when determining whether the non-Federal entity is qualified for a future Federal award.
- c. Upon termination of an award, NIH must provide the information required under FFATA to the Federal web site established to fulfill the requirements of FFATA and update or notify any other relevant government-wide systems or entities of any indications of poor performance as required by 41 U.S.C. 417b and 31 U.S.C. 3321. See also the requirements for Suspension and Debarment at 2 CFR Part 180.

NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. However, NIH may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency. Termination may be appealed under NIH and HHS grant appeals procedures (see [Administrative Requirements—Grant Appeals Procedures](#)).

A grant also may be terminated, partially or totally, by the recipient or by NIH with the consent of the recipient. If the recipient decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the recipient of the possibility of termination of the entire grant and allow the recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant.

See [Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost](#) for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated by NIH, terminated at the request of the recipient, or terminated by mutual agreement.

Withholding of support is a decision not to make a non-competing continuation award within the current competitive segment. Support may be withheld for one or more of the following reasons:

- Adequate Federal funds are not available to support the project.
- A recipient failed to show satisfactory progress in achieving the objectives of the project.
- A recipient failed to meet the terms and conditions of a previous award.

- For whatever reason, continued funding would not be in the best interests of the Federal government.

The recipient may appeal NIH's determination to deny (withhold) a non-competing continuation award because the recipient failed to comply with the terms and conditions of a previous award.

### 8.5.3 Other Enforcement Actions

Depending on the nature of the deficiency, NIH may use other means of promoting recipient compliance. Other options available to NIH include, but are not limited to conversion from an advance payment method to a reimbursement method or disallow (deny) all or part of the cost of the activity or action not in compliance. Other actions may include suspension or debarment of an organization or individual under Government-wide Debarment and Suspension rules provided at 45 CFR Part 76, and other available legal remedies, such as civil action. Suspension under 45 CFR Part 76, implementing E.O.s 12549 and 12689, "Debarment and Suspension," is a separate action from the "suspension" of an award as a post-award remedy, as described in [Suspension, Termination, and Withholding of Support](#) above. The subject of debarment and suspension as an eligibility criterion is addressed in [Completing the Pre-Award Process—Determining Eligibility of Individuals](#) and [Public Policy Requirements and Objectives—Debarment and Suspension](#).

### 8.5.4 Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of a grant. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances. NIH guidance on the repayment of grant funds that are unrelated to audit findings can be found on the [OER Web site](#).

### 8.5.5 Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L. 104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for HHS in 45 CFR 30. NIH is required to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

When NIH determines the existence of a debt under a grant, written debt notification will be provided to the recipient. Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent if they are not paid within 30 days from the date the debt notification is mailed to the recipient. Delinquent debts are subject to the assessment of interest, administrative cost charges, and penalties. The interest on delinquent debts accrues on the amount due beginning on the date the debt notification is mailed to the recipient.

If a recipient appeals an adverse monetary determination under 42 CFR Part 50, Subpart D, or 45 CFR Part 16, interest will accrue but assessment will be deferred pending a final decision on the appeal. If the appeal is not successful, interest will be charged beginning with the date the debt notification was mailed to the recipient, not the date of the appeal decision. Interest charges will be computed using the prevailing rate in effect on the date the debt notification is mailed, as specified by the Department of the Treasury and 45 CFR Part 30.13(a)(2).